

RECEIVED

SEP 13 2000

contrast, Hanisch relates to pharmaceutical compositions comprising interferon-beta, a stabilizer and human serum albumin which composition is then lyophilized.

In addition to the obvious difference in that the claimed composition of a low concentration of interferon-beta is stable in the liquid state, Hanisch also differs in that it teaches that human plasma protein factor (PPF) is the preferred stabilizer for low pH formulations (see column 9, lines 43-44). Furthermore, Hanisch also teaches that a mixture of human serum albumin (HSA) and dextrose or HSA alone is preferably used at high pH (column 9, lines 40-42), in contrast to the optional use of albumin in the present invention at low pH. Applicants maintain that there is nothing in Hanisch either alone or in combination with the other cited references that teaches the use of mannitol (a carbohydrate) at low pH in a stable liquid composition containing interferon-beta. On the contrary, Hanisch teaches the use of a protein (PPF) at low pH and a carbohydrate (dextrose) at high pH. Therefore, a person skilled in the art would not have any expectation of success using mannitol, a carbohydrate, to stabilize low concentrations of interferon-beta in a liquid state (not lyophilized) at a low pH. Accordingly, the Examiner is requested to withdraw this rejection.

In light of the foregoing amendments and remarks, it is respectfully submitted that this application is now in condition to be allowed and the early issuance of a Notice of Allowance is respectfully solicited. If there are any issues or amendments the Examiner wishes to discuss, the Examiner is encouraged to contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on September 7, 2000:

Charles C. Achkar

Name of applicant, assignee or  
Registered Representative

*Charles Achkar*  
Signature

September 7, 1999

Date of Signature

EAM/CCA:lac

Respectfully submitted,

*Charles Achkar*

Charles C. Achkar

Registration No.: 43,311

OSTROLENK, FABER, GERB & SOFFEN, LLP  
1180 Avenue of the Americas

New York, New York 10036-8403

Telephone: (212) 382-07002